Remarks

Claims 1-18 are pending. Claims 6-16 have been withdrawn. The Examiner, however, referred to claims 6-16 as being canceled in the Office Action dated February 5, 2004. This is incorrect, as the claims have not been canceled but were merely non-elected. Therefore, a corrected summary of the claim status is requested in the next communication from the Office.

Support for the amendments to the specification are based on MPEP section 2406.01, which states that "The addition of information designating depository, accession number, and deposit date of the deposited cell line in ATCC after the filing date does not violate the prohibition against new matter in 35 U.S.C. 132." (*In re Lundack*, 773 F.2d 1216, 227 USPQ 90).

Rejection under 35 U.S.C. § 112, first paragraph

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to provide an enabling disclosure, because the specification allegedly lacks complete deposit information for the monoclonal antibody deposited as CRL-12604. The specification has been amended herein to recite that the deposit has been made under the Budapest Treaty, and to recite the full address of the depository (ATCC). By signature below, the attorney of record states that (1) the deposit has been accepted by the ATCC under the provisions of the Budapest Treaty, (2) all restrictions upon public access to the deposits will be irrevocably removed upon the grant of a patent on this application, (3) the deposit will be replaced if viable samples cannot be dispensed by the depository, and (4) the deposited biological sample is a biological sample of hybridoma CP7 which is specifically identified in the application as filed. Also enclosed is a copy of an official

certificate of deposit provided by the ATCC (Exhibit A). By the official certificate of deposit and the statements provided herein, applicants have established that the biological material is known and available to the public by way of deposit. Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite because they do not further define the composition of claim 1. The Examiner states that the claims are directed to characteristics of the antigen which antigen is not claimed.

Applicants respectfully traverse. Claim 1 is drawn to an antibody specific for soluble antigen of a *C. parvum* sporozoite. In the method of claims 17 and 18, which depend from claim 1, the antigen is obtained by specific mechanism: a biological mechanism in claim 17 and a mechanical disruption in claim 18. Different antigens are released by the methods of claim 17 and 18 than otherwise would be present in a *C. parvum* sporozoite which was not biologically or mechanically disrupted, and differ from one another. This is because the two types of disruption release different antigens present internally in *C. parvum*, which antigens would not be accessible without such disruption. For example, page 8, lines 22-23 of the specification reads "In a first preferred embodiment of the immunoassay, the oocysts are treated to cause excystation by biological mechanisms. Therefore, only sporozoites from viable oocysts are released." On the other hand, those sporozoites released by mechanical disruption would have been from both viable and non-viable oocysts (page 8, lines 24-26). Furthermore, if the sporozoite were not disrupted at all, a different group of antigens would have been present.

Therefore, claims 17 and 18 specify the nature of the antigen, such as sporozoites from viable oocysts, which necessarily defines the antibody specific for the antigen. Therefore, claims 17 and 18 further define the composition of claim 1, and applicants respectfully request reconsideration and withdrawal of this rejection.

Rejection under 35 U.S.C. § 102

Claims 1-4 and 17-18 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Farrington et al. The Examiner states that Farrington et al. discloses a method for detecting soluble antigen using monoclonal antibodies against *C. parvum* oocysts.

This rejection is respectfully traversed. Claims 1-4 and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. Farrington et al. discloses an "Anti-*Cryptosporidium* oocyst monoclonal antibody". However, the antibody of Farrington et al. is neither specific for *C. parvum*, as it is described as a *Cryptosporidium* oocyst monoclonal antibody and not just as a *C. parvum* antibody (page 9, 2nd paragraph), nor is the antigen soluble, as Farrington et al. states "Soluble *or finely particulate* antigen was detected...using the MAb C1" (page 14, first full paragraph, emphasis added.) Therefore, since Farrington et al. were not even sure if they were detecting soluble antigens or finely particulate antigen, and since have no evidence to show detection of soluble antigens, this reference cannot be relied upon as prior art. Furthermore, since the assay was capable of detecting both soluble and finely particulate antigen, the antibody is not *specific* for soluble antigen. Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1, 3, 4, and 17-18 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Moss et al. The Examiner states that Moss et al. discloses rabbit antiserum against soluble proteins from *C. parvum* oocysts.

Applicants respectfully traverse. Claims 1, 3, 4, and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. The antibodies of Moss et al. are not *specific* for a soluble antigen of *C. parvum*. Although Moss et al. discloses soluble antigens, nowhere in the paper is it disclosed that the antibodies directed to the soluble antigens are *specific* for soluble antigens. In fact, the abstract states to the contrary: "These results show that lymphocytes from lymph nodes of mice exposed to *C. parvum* oocysts proliferate when cultured *in vitro* with soluble *or particulate antigens* prepared from oocysts." (Emphasis added). Furthermore, page 394, left column, last paragraph discloses the source of antibodies used in the experiments. Rabbit antiserum was prepared against oocysts only, not soluble portions of the oocysts. Furthermore, monoclonal antibody C8C5 disclosed on page 394, top right column, is specific for the 23-kD antigen, which is found on the surface of sporozoites, and therefore not soluble (page 393, top right column.) Also, Figure 2 shows that the antibodies of Moss et al. recognized both soluble proteins and insoluble proteins. Therefore, since both insoluble and soluble antigens were detected by the antibodies of Moss et al., the antibodies are not specific for soluble antigen. Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1- 4, and 17-18 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Perryman et al. The Examiner states that Perryman et al. discloses antibodies specific to *C. parvum* sporozoites.

Applicants respectfully traverse. Claims 1-4 and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. The antibodies of Perryman et al. are not specific for a soluble antigen. On page 13, lines 8-15, Perryman et al. discloses mAb shown to bind peptide epitopes of *C. parvum* antigens. Two distinct epitopes are found within p23, which are *surface glycoproteins* of *C. parvum* sporozoites. Since these epitopes are within the *surface* glycoprotein, the corresponding antibodies cannot be specific for a *soluble* antigen. Perryman et al. does not teach or suggest that the glycoprotein is soluble. Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1- 4, and 17-18 are rejected under 35 USC 102(b) as allegedly being anticipated by Petersen et al. The Examiner states that Petersen discloses monoclonal antibodies to a soluble *C. parvum* sporozoite glycoprotein.

Applicants respectfully traverse. Claims 1-4 and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. First of all, Petersen does not disclose that the antigen is soluble. Although Petersen states that "the >900,000-M_r protein is N glycosylated and Triton X-100 soluble," (page 5135, left col.), this does not mean that the antigen is soluble under normal cellular conditions. For example, the Sigma Product Information Sheet for Triton X-100 (Exhibit B) discloses that Triton X-100 is "often used in biochemical reactions to solubilize proteins". Triton X-100 is able to solubilize

proteins that would not have otherwise been soluble under other conditions. Furthermore, Petersen et al. discloses three antibodies that react with a 900,000-M_r antigen, MAbs 10C6, 7B3, and E6 (page 5134, right col.) Petersen et al. discloses that 10C6 also reacts with intracellular merozoites, and is therefore not specific for a sporozoite antigen (page 5135, left col.). Petersen discloses that 7B3 also recognizes a 38,000-M_r molecule present in oocysts but not sporozoites and is therefore not specific for a sporozoite antigen. Lastly, Fukumoto et al. (*Clin. Diag. Lab. Immunol.* 10(4) 596-601, July 2003) discloses that MAb E6 is also reactive with *Babesia gibsoni* merozoites, and is therefore not specific for *C. parvum* sporozoites (Exhibit C). Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1- 4 and 17-18 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by Riggs et al. The Examiner states that Riggs et al. discloses compositions comprising monoclonal antibodies to *C. parvum* sporozoites.

Applicants respectfully traverse. Claims 1-4 and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. Riggs et al. discloses five MAbs were found to give a posteriorly capped staining on sporozoites with posteriorly extruded fluorescent material, suggesting the presence of shed antigens. However, Riggs et al. also discloses that "these [five] MAbs were found to bind to oocyst walls." (page 7, lines 20-24). Therefore, these monoclonal antibodies are not specific for sporozoites as they also bind oocyst walls. Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1- 4 and 17-18 are rejected under 35 USC 102(b) as allegedly being anticipated by Tilley et al. The Examiner states that Tilley discloses monoclonal antibodies that bind sporozoite surface and apical complex antigens.

Applicants respectfully traverse. Claims 1-4 and 17-18 are drawn to a composition comprising an antibody specific for a soluble antigen of a *C. parvum* sporozoite. Tilley et al. teaches antibodies against sporozoite surface, apical surface, and inner oocyst wall (Table 1). Those antibodies reactive against sporozoite and apical surface are not soluble by definition, as they are present on the surface of the bacteria. Furthermore, these antibodies were shown to react with both the sporozoite and merozoite surface (page 238, left col.) and are therefore not sporozoite specific. The one antibody against the internal oocyst wall, mAb2D7, was not only "unstable" but also not shown to be specific (page 238, right col.). Therefore, applicants respectfully request reconsideration and withdrawal of this rejection.

Pursuant to the above remarks, reconsideration and allowance of the pending application is believed to be warranted. The Examiner is invited and encouraged to directly contact the undersigned if such contact may enhance the efficient prosecution of the application to issue.

A Credit Card Payment Form PTO-2038 authorizing payment in the amount of $110.00, representing the extension of time fee is enclosed. This amount is believed to be correct;

however, the commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

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I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Gwendolyn D. Spratt — Date: 6-7-04